

### Office Action Summary

**Application No.**

10/663,176

**Applicant(s)**

EBERL ET AL.

**Examiner**

Roy D. Gibson

**Art Unit**

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2/12/2008 (telecon).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 16-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-11, 13, 14, 16-32 and 35 is/are allowed.
- 6) ☒ Claim(s) 1-7, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Supplemental Office Action***

This Office action replaces the Final Rejection mailed on 10/15/2007. In a phone interview with Michael Bolen on 10/29/2007, the examiner agreed that if the balloon of Lim et al. did not have pores or holes it would not be capable of chemical ablation and that the application may be in condition for allowance. After an additional search, the examiner found other prior art references and agreed with Mr. Bolan during a second phone interview on Feb. 12, 2008, to provide this supplemental non-final Office action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 12 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lim et al. (6,488,688) in view of Wallsten (7,156,860).

Regarding claims 1, 6, 7 and 12, Lim et al. disclose a medical device (stent deploying catheter system and balloon catheter) with an elongate shaft and an inflatable semi-compliant balloon located on the elongate shaft comprising a polymer made from the same material as claimed and of a thickness as claimed (Tecophilic which is equivalent to Tecoflex as stated by Applicant on page 7 of the Specification and with a wall thickness of the balloon disclosed as 0.0015" or within the claimed range of 0.0005-0.005"), therefore, the balloon, when hydrated with an electrolytic solution, would

inherently have the same tensile strength when inflated to about one atmosphere (col. 3, line 59-col. 4, line 6, col. 5, lines 48-66 and col. 6, lines 35-50). But, Lim et al. fail to specifically disclose the balloon is an "inflation" balloon, interpreted to mean the balloon is heated to a temperature for a sufficient time to ablate tissue. However, Wallsten discloses a stent deployment catheter system with means for heating the balloon to between 60 and 90 deg. C which is capable of ablating tissue (col. 10, line 4-col. 11, line 3). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Lim et al., as taught by Wallsten, to provide the additional treatment capability of heating/ablating the target tissue.

Regarding claim 2, the semi-compliant balloon can be expanded by 4% radially when inflated by 10.2 atm (col. 3, lines 47-51).

Regarding claim 3, Table 1 of Lim et al. in col. 8, discloses the semi-compliant balloon OD increases by about 50% at 195 psi.

Regarding claims 4 and 5, the examiner maintains that the balloon of Lim et al. would inherently be capable of hydration from 10-40% volume (col. 8, line 54).

Regarding claims 33 and 34, Lim et al. disclose the device is configured to be intra-vascularly introduced within a heart of the patient.

***Allowable Subject Matter***

Claims 8-11, 13, 14, 16-28, 29-32 and 35 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/  
Primary Examiner  
Art Unit 3739

February 20, 2008

